

EXHIBIT E

1 IN THE UNITED STATE DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4
5 IN RE: ETHICON, INC. PELVIC REPAIR : Master File No.
6 SYSTEM PRODUCTS LIABILITY : 2:12-MD-02327
7 LITIGATION : MDL No. 2327
8 THIS DOCUMENT RELATES TO : JOSEPH R. GOODWIN
9 PLAINTIFFS: : U.S. DISTRICT JUDGE
10 Kathleen Wolfe 2:12-cv-00335 :
11 Cindy Smith 2:12-cv-01149 :
12 Patricia Conti 2:12-cv-00516 :
13 Marty Babcock 2:12-cv-01052 :
14 Patti Ann Phelps 2:12-cv-01171 :
15 Karyn Drake 2:12-cv-00747 :
16
17 DEPOSITION OF NICOLETTE HORBACH, M.D.
18 Washington, D.C.
19 March 25, 2016
20 10:30 a.m.
21
22
23
24 Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

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9	9
10	10 O'Melveny & Myers LLP
11	11 1625 Eye Street, NW
12	12 Washington, DC 20006
13	13
14	14
15	15
16	16 Taken pursuant to applicable Rules of Civil
17	17 Procedure, before Linda S. Kinkade, Registered
18	18 Diplomate Reporter, Certified Realtime Reporter,
19	19 Registered Professional Reporter, Registered Merit
20	20 Reporter, Certified Shorthand Reporter, as licensed
21	21 by the State of California, and Notary Public, as
22	22 commissioned by the District of Columbia.
23	23
24	24
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1 APPEARANCES:	1 E X H I B I T S
2	2
3 On Behalf of Plaintiffs in the MDL Litigation:	3 NO. DESCRIPTION PAGE
4 Wagstaff & Cartmell, LLP	4 Exhibit 1 Three-ring binder Nicolette S. 7
5 By: Thomas P. Cartmell, Esquire	5 Horbach, M.D. Expert Report
6 (Telephonic appearance)	6 dated 2/25/16 with Cited
7 4740 Grand Avenue	7 Articles and contents thereof,
8 Suite 300	8 including Horbach TVT General
9 Kansas City, Kansas 64112	9 Report & Sources with Tabs 1
10 tcartmell@wcllp.com	10 through 48
11	11 Exhibit 2 Pages 5-8 of Document 75 filed 7
12	12 03/22/16
13	13 Exhibit 3 Hansen: Long-Term Follow-up of 7
14	14 Treatment for Synthetic Mesh
15 On Behalf of Defendant Ethicon and Johnson &	15 Complications
16 Johnson:	16 Exhibit 4 Device Labeling Guidance #G91-1 7
17 Riker Danzig Scherer Hyland Perretti LLP	17 (blue book memo) (Text only)
18 By: Kelly Strange Crawford, Esquire	18 General Program Memorandum
19 One Speedwell Avenue	19 Exhibit 5 U.S. Food and Drug 7
20 Morristown, New Jersey 07962	20 Administration: What is a
21 kcrawford@riker.com	21 Serious Adverse Event?
22	22 Exhibit 6 NIA Adverse Event and Serious 7
23	23 Adverse Event Guidelines
24	24

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1 Exhibit 7 Journal of Clinical Research 2 Best Practices Adverse Event 3 Terminology	7	1 Dr. Horbach had coming into this deposition today. 2 MR. CARTMELL: Thanks, Kelly, for that. 3 I do think that is a fair representation of the 4 agreement that was made among the parties. I will 5 say this, though. I think it was represented to us 6 as plaintiff's counsel in the MDL that the doctor 7 does not have any new opinions that have arisen 8 related to the TTV Retropubic product that she's 9 giving opinions on in this case, and, therefore, 10 this was just going to be a general update 11 deposition limited, as you said, to one hour. If 12 in fact she does have additional opinions, then 13 we'll have to revisit that. Fair enough?	
7 Exhibit 8 Gynecare TTV Tension-free 8 Support for Incontinence	7	14 MS. CRAWFORD: Fair.	
9 Exhibit 9 Handwritten document "174 10 general"	7	15 EXAMINATION	
11		16 BY MR. CARTMELL:	
12		17 Q. Good morning, doctor. As I said, my 13 name is Tom Cartmell, and I represent the 14 plaintiffs in this case. We've never met before; 15 is that correct?	
16		21 A. Yes.	
17		22 Q. And you are in, I understand it, you are 18 in Washington, D.C. right now; is that correct?	
18		24 A. Yes.	
19			
20			
21			
22			
23			
24			
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1 P R O C E E D I N G S 2 (Exhibit 1 was marked for identification.) 3 (Exhibit 2 was marked for identification.) 4 (Exhibit 3 was marked for identification.) 5 (Exhibit 4 was marked for identification.) 6 (Exhibit 5 was marked for identification.) 7 (Exhibit 6 was marked for identification.) 8 (Exhibit 7 was marked for identification.) 9 (Exhibit 8 was marked for identification.) 10 (Exhibit 9 was marked for identification.)		1 Q. I'm actually doing this deposition by 2 phone, which I know is not ideal, so I would just 3 ask that, if you can't understand me for any reason 4 or just don't understand a question, or can't hear 5 me, just ask me to rephrase it and I'll do that. 6 Okay?	
11		7 A. That's fine, yes.	
12		8 Q. You understand that you have been 13 identified as a general causation expert related to 14 the TTV Retropubic product in Wave 1 of the Ethicon 15 MDL? Do you understand that?	
13		12 A. Yes, I think I understand Wave 1 is this 14 group of patients that are being presented, yes.	
14		14 Q. Okay. And do you understand that you 15 have been identified to give general opinions 16 related to the TTV Retropubic product manufactured 17 by Ethicon?	
15		18 A. Yes.	
16		19 Q. Now when I refer to TTV Retropubic, do 17 you understand that I am referring to the product 18 that was manufactured and initially brought to 19 market by Ethicon, I believe in January of 1998, in 20 the United States?	
19		24 A. Yes.	
20			
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22			
23			
24			

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<p>1 Q. And you understand, I take it, from your 2 prior depositions that there's actually two 3 versions of the TVT Retropubic product that 4 continue to be sold, one in the laser-cut mesh or 5 with the laser-cut mesh, and one with the 6 mechanical-cut mesh; is that correct?</p> <p>7 A. Yes.</p> <p>8 Q. Are your opinions in this case, meaning 9 the Wave 1 litigation that you've been identified 10 in, going to be related to both the mechanical-cut 11 versions of the TVT Retropubic product and the 12 laser-cut versions?</p> <p>13 A. Yes.</p> <p>14 Q. And I take it that all of your opinions 15 related to the safety and efficacy of those 16 products, including the laser-cut version and the 17 mechanical-cut version, are contained in your 18 report that you have produced in this litigation; 19 is that correct?</p> <p>20 A. Yes.</p> <p>21 Q. Now I want to, if we can, go through 22 quickly the materials you brought with you today, 23 but actually, before I do that, let me go back to 24 your identification in this wave of Ethicon cases</p>	<p>1 Q. Did you bring that with you today?</p> <p>2 A. No.</p> <p>3 Q. Okay. Why is that?</p> <p>4 MS. CRAWFORD: We were instructed that 5 this was general only and not case specific.</p> <p>6 MR. CARTMELL: Okay.</p> <p>7 THE WITNESS: Correct, that's what I was 8 told.</p> <p>9 BY MR. CARTMELL:</p> <p>10 Q. Doctor, that Drake case that you've been 11 identified in, do you know whether the TVT 12 Retropubic product that was implanted in Ms. Drake 13 was a laser-cut product or a mechanical-cut 14 product?</p> <p>15 MS. CRAWFORD: I'm going to object just 16 because I don't know that the doctor is prepared to 17 respond to questions about Drake because it wasn't 18 contemplated it would be covered at this deposition 19 today, but if she's able to answer it and you want 20 to ask that during your hour, I'm going to let her 21 answer the question.</p> <p>22 THE WITNESS: Okay. I can't answer that 23 for you at this point. I didn't prepare for that 24 part.</p>
<p style="text-align: center;">Page 11</p> <p>1 called Wave 1 by the parties and the court. 2 You've also been identified to give 3 case-specific opinions in one case; is that right?</p> <p>4 A. Yes. Drake.</p> <p>5 Q. The plaintiff's name or the patient's 6 name in that case is Ms. Drake; is that right?</p> <p>7 A. Yes, that's correct.</p> <p>8 Q. And is that the only case that you have 9 been identified to give case-specific opinions in?</p> <p>10 MS. CRAWFORD: For Wave 1?</p> <p>11 MR. CARTMELL: Yes. Sorry.</p> <p>12 THE WITNESS: I believe so. I've been 13 asked to give opinions for another patient, but I 14 don't think she's in Wave 1.</p> <p>15 BY MR. CARTMELL:</p> <p>16 Q. Okay. I'll get to that in a minute.</p> <p>17 With respect to the Drake case that you are 18 identified as an expert, case-specific expert in, I 19 take it you've reviewed Ms. Drake's medical 20 records; is that correct?</p> <p>21 A. Yes.</p> <p>22 Q. And you produced a report related to 23 that?</p> <p>24 A. Yes.</p>	<p style="text-align: center;">Page 13</p> <p>1 BY MR. CARTMELL:</p> <p>2 Q. Okay. And let me just ask, have you 3 ever looked to determine that? In other words, you 4 knew at one time; you're just not prepared to 5 answer that today.</p> <p>6 MS. CRAWFORD: Objection. You can 7 answer.</p> <p>8 THE WITNESS: Yeah, I'm pretty sure that 9 I had seen the information. I just don't remember 10 since the cases tend to merge together.</p> <p>11 BY MR. CARTMELL:</p> <p>12 Q. Okay. All right. Now let's go through 13 real quickly, if we can, the items that you brought 14 with you, and before we got on the record counsel 15 on behalf of Ethicon, I think, has marked as an 16 exhibit everything that you brought with you. Is 17 that your understanding?</p> <p>18 A. Yes, that's correct.</p> <p>19 Q. My memory is that Exhibit 1 is a binder 20 that you brought with several subparts. Would you 21 just real quickly tell us what is contained in that 22 binder?</p> <p>23 A. The Exhibit 1 binder contains a copy of 24 my general report from February 25th, 2016, a</p>

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<p>1 section involved with the reliance list, which is 2 the information that has been forwarded to me over 3 time by Ethicon, and the third section are the 4 specific articles that are cited in my general 5 report from the February 25th, 2016.</p> <p>6 Q. Thank you. Let me ask a few follow-up 7 questions. The reliance list that you referred to, 8 was that prepared by you or counsel for Ethicon?</p> <p>9 A. That was prepared by Ethicon.</p> <p>10 Q. Okay. And does that contain all of the 11 articles or documents that you have reviewed and 12 rely on in forming your opinions in this case?</p> <p>13 A. It -- I have not looked at the current 14 reliance list in this particular binder, as I just 15 received the binder last night via Federal Express. 16 These are definitely things that Ethicon has sent 17 me. I have previously in my last deposition 18 brought additional reference list of articles that 19 I had looked at in referring to my -- or in 20 formulating my general report. I don't know 21 whether or not those are specifically included. So 22 there may be additional articles that are not in 23 this reliance list that I myself have pulled and 24 I've used in my opinion.</p>	<p>1 spend my hour looking through these many pages to 2 determine if those additional references that I've 3 used are in the reliance list. Part of the 4 difficult --</p> <p>5 Q. Is your --</p> <p>6 A. Go ahead.</p> <p>7 Q. Go ahead.</p> <p>8 A. No, I'm fine. Thank you.</p> <p>9 Q. Now I've looked at that reliance list, 10 and there are hundreds of articles, if not a 11 thousand, and thousands and thousands of pages of 12 documents. Fair to say that, to review all of that 13 information on your reliance list, would take you 14 hundreds and hundreds of hours to review if you 15 reviewed all those pages?</p> <p>16 MS. CRAWFORD: Objection. You can 17 answer.</p> <p>18 THE WITNESS: I can't tell you how many 19 hours it would take me, but I know I've definitely 20 worked hundreds of hours on this particular issue.</p> <p>21 BY MR. CARTMELL:</p> <p>22 Q. Okay. And so without going through each 23 and every item on that reliance list, it would be 24 hard for you to say today which of those you have</p>
<p style="text-align: center;">Page 15</p> <p>1 Q. Okay. Thank you for that. Have you 2 actually looked at all of the documents that are 3 identified on your reliance list that is in the 4 binder marked Exhibit 1?</p> <p>5 A. I've looked at the bulk of them. I 6 don't know whether I could tell you that I've read 7 every single one of them because sometimes I may 8 not have felt that they were applicable to what I 9 was looking for for my opinion. And, in addition, 10 there are information in here that's actually part 11 of Prolift documents that were sent to me in my 12 review of Prolift.</p> <p>13 Q. Okay. So is it fair to say that there 14 may be some information on that reliance list that, 15 for one reason or another, you have not actually 16 reviewed and are not actually relying on in forming 17 your opinions in this case?</p> <p>18 A. Correct.</p> <p>19 Q. And now --</p> <p>20 A. Sorry.</p> <p>21 Q. I'm sorry. Go ahead.</p> <p>22 A. I'm just saying, and there may -- and 23 there may be other documents that aren't included 24 specifically in the reliance list, again, unless I</p>	<p style="text-align: center;">Page 17</p> <p>1 reviewed or which you haven't reviewed, correct?</p> <p>2 A. Without going through each individual 3 one, no.</p> <p>4 Q. And I take it there is information on 5 that reliance list that, rather than look at the 6 information in detail, you have skimmed, for 7 example, the information; is that fair?</p> <p>8 A. There may be, yes, part of what's listed 9 here I may have skimmed rather than read word for 10 word.</p> <p>11 Q. I see. Now all of the documents on 12 there that are internal corporate documents 13 produced confidentially in this litigation, were 14 those all provided to you by defense counsel?</p> <p>15 A. If it's listed in the reliance list, it 16 is my assumption that they were all sent to me.</p> <p>17 Q. Were there any internal corporate 18 documents from Ethicon or Johnson & Johnson that 19 you specifically requested to see related to the 20 TVT Retropubic product?</p> <p>21 A. Probably I have, although I can't 22 specifically tell you which since I started 23 reviewing this back in 2012 or '13, so it's been 24 quite some time.</p>

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<p>1 Q. I don't have your reliance list 2 obviously that is in Exhibit 1. When did you say 3 that that was provided to you? 4 A. I received it yesterday by Federal 5 Express. 6 MS. CRAWFORD: Tom, it's Kelly. I 7 apologize if this isn't the case, but normally that 8 reliance list is the Exhibit B to the expert 9 report. It's normally produced with it. If that 10 didn't happen in this case, we can certainly follow 11 up on that, but I would have assumed that that 12 happened.</p> <p>13 MR. CARTMELL: I appreciate that, Kelly. 14 I'm not certain whether or not it was or wasn't. I 15 just don't know if that one in the exhibit is any 16 different than the reliance list that we have, and 17 we do have one.</p> <p>18 MS. CRAWFORD: Okay.</p> <p>19 MR. CARTMELL: So I don't know if there's 20 been any updates since the one that was provided to 21 us. Do you know that, Kelly?</p> <p>22 MS. CRAWFORD: I don't know the answer to 23 that and I'll find out for you.</p> <p>24 MR. CARTMELL: Okay. Thank you.</p>	<p>1 your deposition in December of 2015 in the Corbet 2 case, at that time your testimony was you had not 3 reviewed any Ethicon employees' or corporate 4 representatives' depositions as of that time. Do 5 you recall that?</p> <p>6 A. I don't recall stating that. I mean, 7 I've certainly in the past have looked at, I think, 8 David Robinson and one or two of the other 9 corporate depositions. I think that was more 10 related to the Prolift cases.</p> <p>11 And so if I answered it specifically for no 12 for the TVT cases, it may have just been because of 13 separating it out from my perspective rather than 14 putting it all together as one.</p> <p>15 Q. Okay. So is your testimony that, if you 16 testified in the Corbet case that you had not 17 reviewed any corporate witness testimony as of that 18 time, that in fact your testimony at that time was 19 not correct?</p> <p>20 A. That is not what I'm saying. I'm saying 21 if I -- if I answered in my deposition in December 22 that I had not reviewed any corporate employee 23 depositions, that that was specifically answering 24 relative to my preparation of my TVT general</p>
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<p>1 BY MR. CARTMELL: 2 Q. Doctor, are there any depositions 3 included on that reliance list? 4 A. Just a minute. I'll have to look 5 through. 6 Q. You know what, doctor? Let me try to 7 save some time. 8 A. Okay. I'm just sort of going through, 9 because, as I said, there's a fair number of things 10 here. I don't see -- I don't see right now 11 depositions on this, although I know I have 12 depositions that I have reviewed. 13 Q. Okay. And I want to ask you about that 14 right now. I've read your prior testimony in the 15 Corbet case and then in the Wicker case. 16 First of all, what depositions of Ethicon 17 employees have you reviewed? 18 A. Unfortunately, because this was not part 19 of what was -- I was told was going to be covered. 20 I haven't prepared and looked back at all of that 21 in what I've reviewed from the last three or four 22 years to be able to tell you which depositions I've 23 read. 24 Q. Okay. Well, my understanding is from</p>	<p>1 report. It did not necessarily reflect that I have 2 never read them as part of my evaluation of the 3 Prolift.</p> <p>4 Q. Okay. So let's clarify that. Is it 5 still the case today that you have not reviewed any 6 corporate Ethicon employees' depositions in 7 preparation for your opinions related to the TVT 8 product?</p> <p>9 A. I think that is accurate, yes.</p> <p>10 Q. Okay. And you had, I take it from your 11 prior answer, reviewed corporate representatives' 12 testimony related to the Prolift product; is that 13 right?</p> <p>14 A. Yes.</p> <p>15 Q. And you mentioned David Robinson's 16 deposition. Have you reviewed any other corporate 17 representatives' or employees' depositions related 18 to the Prolift product?</p> <p>19 A. Yes.</p> <p>20 Q. Who else?</p> <p>21 A. I can't possibly tell you. That was a 22 while back and I'm very bad with names.</p> <p>23 Q. Can you name any additional witnesses 24 whose depositions you may have read related to the</p>

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<p>1 Prolift product?</p> <p>2 A. I said, no, I can't. Unfortunately, as</p> <p>3 I said, I'm very bad with names, so I can't -- his</p> <p>4 name I recall, but I don't recall the other names.</p> <p>5 Q. Okay. All right. So let's continue</p> <p>6 naming or identifying what you have marked. My</p> <p>7 understanding is that Exhibit 2 is the notice or</p> <p>8 portions of the notice for deposition today; is</p> <p>9 that correct?</p> <p>10 A. Yes.</p> <p>11 Q. Why don't you, if you wouldn't mind,</p> <p>12 going through Exhibits 3 through 9 -- I believe 9</p> <p>13 is the last exhibit that you identified -- go ahead</p> <p>14 and tell us briefly on the record what each of</p> <p>15 those exhibits is, please.</p> <p>16 A. Exhibit 3 is an article by Hansen</p> <p>17 entitled Long-Term Follow-Up of Treatment for</p> <p>18 Synthetic Mesh Complications, and, in addition,</p> <p>19 there are the abstracts of several articles</p> <p>20 referenced in the Hansen article that are attached</p> <p>21 to that exhibit.</p> <p>22 Q. Okay. And is that an article that you</p> <p>23 brought specifically with you to the deposition</p> <p>24 today?</p>	<p>1 ever reviewed any FDA guidelines or guidance</p> <p>2 documents related to labeling of medical devices?</p> <p>3 A. Not that I can recall.</p> <p>4 Q. Okay. Go ahead and continue, please.</p> <p>5 A. The Exhibit 5 is listed as the FDA "What</p> <p>6 is a serious adverse event?" definitions.</p> <p>7 Q. Again, the same question. Is that</p> <p>8 something you just received recently?</p> <p>9 A. No, I pulled that myself.</p> <p>10 Q. When did you pull that?</p> <p>11 A. Recently in preparation for the</p> <p>12 deposition.</p> <p>13 Q. Okay. So, for example, as of the time</p> <p>14 of writing your report, that's not something that</p> <p>15 you had reviewed or relied on in developing your</p> <p>16 opinions, fair?</p> <p>17 A. No. I mean, that's part of -- it is</p> <p>18 confirmatory information for what I was already</p> <p>19 aware of, but it's just specifically laid out in</p> <p>20 detail, and I had reviewed previously information</p> <p>21 on serious adverse events and different criteria</p> <p>22 that have been used for defining serious adverse</p> <p>23 events in preparation for my prior general report.</p> <p>24 Q. I understand, but as far as the contents</p>
Page 23	Page 25
<p>1 A. Yes.</p> <p>2 Q. Why is that? That's a poor question.</p> <p>3 Sorry.</p> <p>4 Why is it that you specifically brought that</p> <p>5 article? Is it something you recently received or</p> <p>6 why did you bring that?</p> <p>7 A. Because I was asked to bring all of the</p> <p>8 documents in my possession that I have relative to</p> <p>9 this issue and that's a more recent -- I pulled</p> <p>10 those articles or those abstracts more recently.</p> <p>11 Q. All right. Go ahead and continue,</p> <p>12 please.</p> <p>13 A. The next is Exhibit 4 that is listed as</p> <p>14 a General Program Memorandum from 1991 from the FDA</p> <p>15 regarding device labeling guidance.</p> <p>16 Q. Was that provided to you or is that</p> <p>17 something you looked for?</p> <p>18 A. Part of this was provided to me and part</p> <p>19 of it I looked for.</p> <p>20 Q. Okay. And when was the first time you</p> <p>21 saw that document?</p> <p>22 A. Fairly recently, in the last week or</p> <p>23 two.</p> <p>24 Q. Before reviewing that document, had you</p>	<p>1 of that document, that is, Exhibit 5, is that</p> <p>2 information that you had reviewed, that specific</p> <p>3 information included in that document, prior to</p> <p>4 writing your report in this case?</p> <p>5 A. This particular document I had not seen</p> <p>6 prior to my report, but the information within the</p> <p>7 document I was aware of prior to my report.</p> <p>8 Q. Okay. Go ahead and continue, please.</p> <p>9 A. The next is from the NIH, The National</p> <p>10 Institutes, on aging, and it's their guidelines</p> <p>11 regarding adverse events and the definition of</p> <p>12 serious adverse events guidelines.</p> <p>13 Q. When was the first time you reviewed</p> <p>14 that document?</p> <p>15 A. This particular one that I pulled,</p> <p>16 again, I reviewed it fairly recently. I have seen</p> <p>17 similar documentation previously.</p> <p>18 Q. Okay. And that's on your reliance list,</p> <p>19 the similar documentation?</p> <p>20 A. I would have to look through to make</p> <p>21 sure that it is.</p> <p>22 Q. Just so it's clear for the testimony, is</p> <p>23 it your testimony under oath that the information</p> <p>24 contained in that exhibit you had actually seen</p>

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<p>1 prior to writing your report?</p> <p>2 A. Correct.</p> <p>3 Q. Okay. Continue, please.</p> <p>4 A. Exhibit 7 is an article from what's</p> <p>5 called the Journal of Clinical Research Best</p> <p>6 Practices, and it is entitled -- it is an article</p> <p>7 entitled Adverse Event Terminology, and it lists</p> <p>8 different adverse event definitions that are used</p> <p>9 by different organizations, including the U.S. Drug</p> <p>10 Regulations, the National Cancer Institute, Medical</p> <p>11 Device Regulations Guidance and ISO Guidelines,</p> <p>12 European Directive and Guidelines.</p> <p>13 Q. Okay. When is the first time you</p> <p>14 received and reviewed that document?</p> <p>15 A. I pulled this document myself as an</p> <p>16 example of the different variations on what is used</p> <p>17 to define an adverse event, and I pulled that in</p> <p>18 preparation for this deposition.</p> <p>19 Q. Had you seen that prior to the time of</p> <p>20 writing your report?</p> <p>21 A. This specific document itself, no; parts</p> <p>22 of the document, yes.</p> <p>23 Q. Okay. What else? You can continue,</p> <p>24 please.</p>	<p>1 the current general report from February is</p> <p>2 essentially a combination of those two reports with</p> <p>3 a couple additional statements in it.</p> <p>4 Q. So is it fair to say that you first saw</p> <p>5 the revised or new IFU from 2015 for the TTVT</p> <p>6 Retropubic product in or around November of 2015;</p> <p>7 is that fair?</p> <p>8 A. No, I said prior to -- in preparing that</p> <p>9 report, and I can't say whether it was in February</p> <p>10 of 2015 or in October of 2015.</p> <p>11 Q. Can you ballpark it?</p> <p>12 A. No.</p> <p>13 Q. Okay. And with respect -- okay. Why</p> <p>14 don't you go ahead and continue with Exhibit 9,</p> <p>15 please.</p> <p>16 A. And the last, Exhibit 9, is a</p> <p>17 handwritten statement by me saying "174 general."</p> <p>18 Q. When did you write that piece of paper</p> <p>19 marked as Exhibit 9?</p> <p>20 A. This morning.</p> <p>21 Q. And what does that reflect or refer to?</p> <p>22 A. I was asked to produce information</p> <p>23 regarding the number of hours that I had spent in</p> <p>24 preparation of review of the literature and</p>
<p style="text-align: center;">Page 27</p> <p>1 A. Exhibit 8 is the TTVT instructions for</p> <p>2 use that is the most recent -- the most recent</p> <p>3 version.</p> <p>4 Q. I think that you're referring to the</p> <p>5 2015 IFU that was released that has additional</p> <p>6 warnings and adverse reactions in it; is that</p> <p>7 right?</p> <p>8 A. It's the one that was released in</p> <p>9 January 2015.</p> <p>10 Q. When is the first time that you had seen</p> <p>11 that new IFU that was actually released related to</p> <p>12 the TTVT Retropubic product in 2015?</p> <p>13 A. During the formulation of my</p> <p>14 supplemental report.</p> <p>15 Q. Supplemental report in this case?</p> <p>16 A. Yes, the supplemental report was back</p> <p>17 in, I think, November or so of 2015 when I wrote</p> <p>18 that.</p> <p>19 Q. Are you talking about your report, your</p> <p>20 supplemental report, in the Corbet case?</p> <p>21 A. I'm not sure how you term it, but there</p> <p>22 was the original general report from July of 2014,</p> <p>23 there was a supplemental general report submitted</p> <p>24 in either November or December of 2015, and then</p>	<p style="text-align: center;">Page 29</p> <p>1 preparation of my -- my general reports in the TTVT</p> <p>2 situation, and that represents my best ability to</p> <p>3 put that together.</p> <p>4 Q. Okay. Let me follow up on that a bit.</p> <p>5 Now, I know that you testified in the past</p> <p>6 that you first became a consultant in litigation for</p> <p>7 Ethicon in, I believe, 2012; is that fair?</p> <p>8 A. I think it was around 2012, yes.</p> <p>9 Q. Okay. And since that time my</p> <p>10 understanding is that you have given depositions in</p> <p>11 a case called Corbet and a case called Wicker, and</p> <p>12 I believe there might be one more prior to today;</p> <p>13 is that correct?</p> <p>14 A. That's correct. There are three -- I'm</p> <p>15 sorry. I've given three depositions that I recall.</p> <p>16 Q. Do you remember the case name in the</p> <p>17 other deposition, the third that I did not mention?</p> <p>18 A. It was -- I was deposed as just a</p> <p>19 general expert. That was the deposition in</p> <p>20 December -- on December 23rd, 2015.</p> <p>21 Q. Okay. I think that was the Corbet</p> <p>22 deposition, but --</p> <p>23 MR. CARTMELL: Do you know, Kelly, was</p> <p>24 it --</p>

<p style="text-align: right;">Page 30</p> <p>1 MS. CRAWFORD: No, she was deposed in -- 2 prior to the Corbet trial sitting as a general 3 expert.</p> <p>4 THE WITNESS: I've not been deposed on 5 Corbet as a -- as the case-specific expert. I 6 think the other deposition was actually Schubert, 7 you're correct, as a Prolift. So Wicker and 8 Schubert for Prolift, and then TVT deposition as a 9 general expert, not as a case-specific expert.</p> <p>10 BY MR. CARTMELL:</p> <p>11 Q. Okay. I appreciate you clarifying that. 12 Okay.</p> <p>13 So this number of 174 that you've listed this 14 morning on Exhibit 9, is that the number of hours 15 that you have actually spent in preparing your 16 opinions prior to today related to the Wave 1 cases 17 only?</p> <p>18 A. Again, the Wave 1 issue is something I'm 19 not quite as familiar with. It is the number of 20 hours I've spent to prepare the general reports, 21 the different versions of general reports, that you 22 all have on specifically just the midurethral 23 slings.</p> <p>24 Q. I see. And those reports are just</p>	<p style="text-align: right;">Page 32</p> <p>1 about your -- related to your TVT-R opinions in 2 this case and in the cases that you testified about 3 TVT-R. How much of that time has involved actual 4 review of the documents on your reliance list, your 5 best guess?</p> <p>6 A. I would say -- as I said, I can't really 7 tell you because it's been a combination of 8 reviewing the articles on the reliance list, doing 9 my own research in the library and pulling my own 10 articles that I wanted to review, and the writing 11 part. So it's hard for me to really give you 12 specifics about how many hours I did what.</p> <p>13 Q. Well, give me your best guess on 14 reviewing materials.</p> <p>15 A. I can't -- I mean, it would still -- I 16 just can't give you an accurate guess.</p> <p>17 Q. You can't give me any sort of 18 guesstimate of how much time you've spent reviewing 19 materials related to your opinions; is that fair?</p> <p>20 A. I mean, essentially the time has been 21 either meeting, review of materials or writing, 22 so ...</p> <p>23 Q. And what I'm trying to do is get your 24 best estimate of how much time that is reviewing</p>
<p style="text-align: right;">Page 31</p> <p>1 referring to the TVT Retropubic, correct? 2 A. It refers to the TVT Retropubic, and I 3 think there's -- it also refers to the TVT Exact. 4 Q. Okay. And so would it be fair for me to 5 say that, prior to today, you have spent 174 hours 6 in developing your TVT Retropubic opinions 7 regardless of whether that includes time meeting 8 with counsel for Ethicon or doing research or 9 writing your report?</p> <p>10 A. Yes, for just -- this does not include 11 any review of patient-specific medical records or 12 depositions.</p> <p>13 Q. Okay. Now of that 174 hours I want you 14 to try to guesstimate for me. How much of that 15 time has been spent meeting with or talking with 16 counsel for defense about TVT Retropubic or Exact?</p> <p>17 A. Maybe 20 or so. It's hard, I mean, it's 18 hard for me to say over a couple of year time 19 period. It could be a little bit more, but not a 20 substantial number of hours.</p> <p>21 Q. Okay. The 20 is your best guess. 22 That's fair enough, right?</p> <p>23 A. Yeah, 20 or 30 at the most, but, yeah. 24 Q. Okay. And then we're still talking</p>	<p style="text-align: right;">Page 33</p> <p>1 materials. You've already told me about your best 2 guess meeting with counsel.</p> <p>3 A. It's probably been maybe 100 plus hours. 4 I don't know.</p> <p>5 Q. Okay. Now all of that 174 hours, has 6 that been at \$500 an hour?</p> <p>7 A. Yes.</p> <p>8 Q. And how much of that 174 hours has been 9 since you actually submitted your report in this 10 case?</p> <p>11 A. I've received zero to date.</p> <p>12 MS. CRAWFORD: I don't think that was the 13 question.</p> <p>14 THE WITNESS: Is that what you're asking?</p> <p>15 BY MR. CARTMELL:</p> <p>16 Q. No, no. Let me restate it. How many of 17 the 174 hours has been spent by you since you 18 actually submitted your Wave 1 report in this case 19 on TVT Retropubic?</p> <p>20 A. Can you specify what report is 21 considered to be the Wave 1 report?</p> <p>22 Q. Well, it's your report. You signed it 23 and submitted it in this case.</p> <p>24 A. I have -- I have three different dates</p>

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<p>1 that I have submitted reports, so I'm asking you --</p> <p>2 Q. Well, let me try and clarify. I don't</p> <p>3 mean to interrupt you, but the one that you brought</p> <p>4 with you today that is marked in Exhibit 1, that</p> <p>5 report is the one I'm talking about.</p> <p>6 A. Okay. Then I think --</p> <p>7 Q. How much of the time has been since</p> <p>8 then?</p> <p>9 A. Probably six or seven hours.</p> <p>10 Q. Okay. And that includes meeting with</p> <p>11 defense counsel and preparing on your own for this</p> <p>12 deposition, I take it.</p> <p>13 A. Correct.</p> <p>14 Q. Okay. Now I want to try to get an</p> <p>15 understanding of how many hours you have spent</p> <p>16 related to your opinions that you've given in mesh</p> <p>17 litigation on the Prolift product. Can you</p> <p>18 ballpark or give me your best estimate on how many</p> <p>19 hours you have spent related to your Prolift</p> <p>20 opinions?</p> <p>21 MS. CRAWFORD: Tom, I'm going to object.</p> <p>22 I specifically didn't ask the doctor to calculate</p> <p>23 that for us today, and I think it would be very</p> <p>24 hard for her to do it and it's not part of the</p>	<p>1 THE WITNESS: The only answer I can give</p> <p>2 you is it's been more hours than what I've done for</p> <p>3 the TVT.</p> <p>4 BY MR. CARTMELL:</p> <p>5 Q. So greater than 174 hours; is that fair?</p> <p>6 A. Correct.</p> <p>7 Q. And is that information that you would</p> <p>8 have available to you? In other words, I take it</p> <p>9 you could find out those -- or that number of</p> <p>10 hours; is that fair?</p> <p>11 A. Correct.</p> <p>12 Q. Okay.</p> <p>13 MR. CARTMELL: And, Kelly, I would just</p> <p>14 ask that you -- and I'll submit something -- that</p> <p>15 you provide us that, and again, if there's an</p> <p>16 objection, we can take it up, but I would like -- I</p> <p>17 think it's discoverable. I think the dispute is</p> <p>18 whether or not at a specific trial if it comes in,</p> <p>19 but I'd ask that you provide me those hours related</p> <p>20 to all of her Prolift work as well. Okay?</p> <p>21 THE WITNESS: Does that include case</p> <p>22 specific or just general?</p> <p>23 MS. CRAWFORD: Why don't you send a</p> <p>24 written request, Tom, and we'll respond to it. I'm</p>
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<p>1 scope of today. We can certainly get that</p> <p>2 information to you at a later time. I mean, I'm</p> <p>3 not going to direct her not to answer the question,</p> <p>4 but I don't think she's prepared to answer that</p> <p>5 today.</p> <p>6 MR. CARTMELL: Okay. Well, I just need</p> <p>7 an answer from her. I guess if your position is</p> <p>8 that, you know, in this general deposition I'm not</p> <p>9 entitled to get, you know, the number of hours she</p> <p>10 spent on mesh litigation, I disagree with that. I</p> <p>11 think you're saying you'll give it to me, but I</p> <p>12 want to know if she has any idea today how many</p> <p>13 hours she has spent in mesh litigation as a</p> <p>14 consultant for Ethicon related to the Prolift or</p> <p>15 other products.</p> <p>16 MS. CRAWFORD: Okay. So just for the</p> <p>17 record I am placing an objection. I understand at</p> <p>18 the national level there's a dispute and a debate</p> <p>19 between the parties as to either party's right to</p> <p>20 the answer to that question that is being resolved</p> <p>21 at a pay grade above mine, and I will allow her to</p> <p>22 answer the question, if she can today, but I do</p> <p>23 believe it's beyond the scope of this deposition</p> <p>24 today.</p>	<p>1 sure you'll get it. If you send me the specific</p> <p>2 request, we'll respond to it.</p> <p>3 MR. CARTMELL: Okay.</p> <p>4 BY MR. CARTMELL:</p> <p>5 Q. Doctor, you just raised a point that I</p> <p>6 want to follow up on. How many case-specific hours</p> <p>7 have you spent reviewing medical records, forming</p> <p>8 opinions in TVT cases?</p> <p>9 MS. CRAWFORD: Objection for the record.</p> <p>10 THE WITNESS: I don't have that specific</p> <p>11 number with me today since this was supposed to be</p> <p>12 general report. However, I've reviewed two</p> <p>13 case-specific records for TVTs, the Drake case --</p> <p>14 MS. CRAWFORD: Before you respond, Tom,</p> <p>15 I'm sorry, I have to interrupt her because I don't</p> <p>16 know the answer to whether or not what she's about</p> <p>17 to tell you is something that she has yet been</p> <p>18 designated or not. And if she hasn't been, I would</p> <p>19 object to the name of that at this point in time as</p> <p>20 work product, and I would direct her not to answer</p> <p>21 that question.</p> <p>22 MR. CARTMELL: That's fair enough. We</p> <p>23 can take it up, if we need to.</p> <p>24 BY MR. CARTMELL:</p>

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<p>1 Q. Let me follow up without the name.</p> <p>2 There are two case-specific TTV cases that you have</p> <p>3 been involved with and spent time on reviewing; is</p> <p>4 that fair?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And can you ballpark for me the</p> <p>7 amount of time you spent in those two cases related</p> <p>8 to, you know, your opinions, whether it be</p> <p>9 reviewing those records or actually drafting</p> <p>10 reports?</p> <p>11 MS. CRAWFORD: Objection. You can</p> <p>12 answer.</p> <p>13 THE WITNESS: Probably 75 to a hundred.</p> <p>14 I think that's probably the best range that I can</p> <p>15 give you. It could be a little more; it could be a</p> <p>16 little bit less.</p> <p>17 BY MR. CARTMELL:</p> <p>18 Q. Okay. And, again, that's information</p> <p>19 that you have available to you and could find,</p> <p>20 fair?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. So but I think what you're saying</p> <p>23 is that we could add 75 to a hundred</p> <p>24 approximately -- and I'm not holding you</p>	<p>1 THE WITNESS: No, I don't believe I've --</p> <p>2 no, I haven't reviewed or been asked to consult on</p> <p>3 any other products.</p> <p>4 BY MR. CARTMELL:</p> <p>5 Q. Okay. I appreciate that. Okay.</p> <p>6 Are there any other documents that we</p> <p>7 haven't already discussed that you brought with you</p> <p>8 today?</p> <p>9 A. I don't believe so.</p> <p>10 Q. Now you testified in the Corbet case --</p> <p>11 well, let me ask you. How is it that you keep</p> <p>12 track of these hours? Do you have an electronic</p> <p>13 document that could be produced that has the hours</p> <p>14 you've spent or how is it that you keep track of</p> <p>15 your hours in the mesh litigation as a whole?</p> <p>16 A. I am sort of an old-fashioned person, so</p> <p>17 I have a paper calendar, and on my paper calendar I</p> <p>18 indicate hours I've spent on a particular day in</p> <p>19 review of the -- in working as an expert in these</p> <p>20 cases.</p> <p>21 Q. And I take it you have maintained those</p> <p>22 back to 2012?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And I noticed in Corbet, as of</p>
<p style="text-align: center;">Page 39</p> <p>1 specifically to the number -- but we could add 75</p> <p>2 to a hundred to the 174, and that would make up all</p> <p>3 of the TTV hours you believe you have spent,</p> <p>4 whether it be case specific or general; is that</p> <p>5 fair?</p> <p>6 A. Yes, that's correct.</p> <p>7 Q. Okay. And the same with respect to</p> <p>8 Prolift. You have case-specific hours that you've</p> <p>9 spent for the Prolift?</p> <p>10 A. Yes.</p> <p>11 Q. And is that also information that you</p> <p>12 could provide, if asked to?</p> <p>13 A. Yes.</p> <p>14 Q. Are there any other products other than</p> <p>15 the TTV Retropubic and the Prolift device that you</p> <p>16 have been asked to offer opinions on related -- and</p> <p>17 I'm talking about Ethicon products.</p> <p>18 MS. CRAWFORD: I'm going to object again</p> <p>19 to the extent it hasn't been designated and it's</p> <p>20 potentially work product, so I want to tread</p> <p>21 carefully here.</p> <p>22 So just answer yes or no. If it's a yes, I</p> <p>23 might have to ask her a question off the record</p> <p>24 before she can answer it.</p>	<p style="text-align: center;">Page 41</p> <p>1 2015, at least with respect to TTV, you had not</p> <p>2 submitted a single invoice related to the work you</p> <p>3 had completed. Is that still the case?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Have you submitted any invoices</p> <p>6 related to the Prolift either case specific or</p> <p>7 general work you've done?</p> <p>8 A. No.</p> <p>9 MS. CRAWFORD: Hey, Tom, just for the</p> <p>10 record, I just want to make sure we're clear.</p> <p>11 Again, while she did testify in advance of the</p> <p>12 Corbet case, it was not Corbet. It wasn't</p> <p>13 captioned Corbet. It was general for the</p> <p>14 New Jersey TTV Retropubic.</p> <p>15 MR. CARTMELL: Okay. I appreciate that.</p> <p>16 Thanks. I've been misstating that.</p> <p>17 BY MR. CARTMELL:</p> <p>18 Q. But I'm actually, when I talk about</p> <p>19 that, talking about your December 2015 deposition;</p> <p>20 is that okay, doctor?</p> <p>21 A. Yes, that's correct.</p> <p>22 Q. You understand that?</p> <p>23 A. I understand.</p> <p>24 Q. Okay. So to this day, even though</p>

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<p>1 you've been working in this litigation for over 2 three years, you still have never sent an invoice 3 or been paid any amount by Ethicon for the work 4 you've done in the mesh litigation as a whole; is 5 that fair?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Why is it that you haven't 8 submitted any invoices?</p> <p>9 A. I think it's a combination of two 10 things. Number one, my life is incredibly busy and 11 crazy and I have hardly enough time to do what I 12 need to do normally, so I get behind on paperwork, 13 and number two is that my reason for doing this is 14 not solely as a financial compensation issue that 15 I'm dependent upon that compensation. I do this 16 because I believe strongly in the product, and 17 the -- and I disagree strongly with the allegations 18 of the plaintiffs' experts regarding the problems 19 associated with this.</p> <p>20 Q. But your intent, I take it, doctor, is 21 to actually submit invoices at some point and be 22 paid, fair enough?</p> <p>23 A. Most likely, yes, at some point.</p> <p>24 Q. Okay. Okay. Is there an agreement you</p>	<p>1 debating that ...</p> <p>2 Q. I don't mean to interrupt you, but I can 3 try to speed this along. You testified in your 4 December 2015 deposition, I believe, that you had 5 not used the TVT Retropubic mesh product for over 6 five years, and I guess my question is: Is that 7 still the case? In other words, you have not used 8 the TVT Retropubic product since December of 2015.</p> <p>9 A. Yes, that's correct. I only use the TVT 10 Exact.</p> <p>11 Q. Okay. And that was -- you anticipated 12 my next question, but how long has it been since 13 you used any other midurethral sling other than the 14 TVT Exact?</p> <p>15 A. I've used both within the last month. 16 I've used Boston Scientific Advantage as well as a 17 TVT Exact within the last month.</p> <p>18 Q. Okay. I thought you said that you only 19 used the TVT Exact, but is it your testimony that 20 to this day you used both the Boston Scientific 21 Advantage and the TVT Exact?</p> <p>22 A. Yes.</p> <p>23 Q. And is there a reason why you might use 24 one or the other? In other words, are there</p>
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<p>1 have with Ethicon related to when you'll be paid?</p> <p>2 A. No.</p> <p>3 Q. Do you have a written consulting 4 agreement with Ethicon related to this litigation?</p> <p>5 A. I don't recall. I think I've been sent 6 documents, but I don't think that I've actually 7 signed it and sent it back.</p> <p>8 Q. Okay. But your memory is that you were 9 sent a contract by Ethicon.</p> <p>10 A. At some point in the last three years, 11 yes.</p> <p>12 Q. Okay. And you still have a copy of 13 that, I take it?</p> <p>14 A. I have no idea.</p> <p>15 MR. CARTMELL: I'm going to ask for that 16 as well, Kelly, just so you'll know, and, doctor, 17 you can look and just let me know if you have it.</p> <p>18 BY MR. CARTMELL:</p> <p>19 Q. Let me move on here. I want to talk now 20 about your use of midurethral slings. Is it fair 21 that you have not used the TVT Retropubic 22 midurethral sling since approximately -- well, tell 23 me when, approximately when.</p> <p>24 A. That's a good question. We were</p>	<p>1 certain patients you use the Exact in and certain 2 patients that you use the Advantage in?</p> <p>3 MS. CRAWFORD: I'm just going to object 4 as beyond the scope of this deposition, but I'll 5 allow her to answer the question.</p> <p>6 THE WITNESS: My decision is not patient 7 specific. My decision is based on other factors.</p> <p>8 BY MR. CARTMELL:</p> <p>9 Q. What are those?</p> <p>10 A. Well, part of it is dependent upon what 11 we have in the room, whether they have pulled the 12 TVT Exact or the Boston Scientific and/or both for 13 being available in the room. Part of it is whether 14 I am at a hospital that doesn't necessarily offer 15 or carry the Boston Scientific sling. One of the 16 hospitals tends to be more Ethicon related. Part 17 of the decision is, when I'm in the process of 18 doing my training for both fellows and residents, 19 to give them the opportunity to use more than one 20 type of sling device so that they can determine 21 which one they may prefer.</p> <p>22 Q. Okay. Thank you. Now you testified 23 previously that you were implanting 100 plus 24 midurethral slings per year. Is that still the</p>

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<p>1 case?</p> <p>2 A. Yes.</p> <p>3 Q. And so, for example, in 2015 your</p> <p>4 testimony is that you personally would have</p> <p>5 implanted 100 plus midurethral slings; is that</p> <p>6 fair?</p> <p>7 A. Yes. 2015 may have been a few less</p> <p>8 because I had surgery myself, and so I was out of</p> <p>9 the office for two months, so ... but typically</p> <p>10 that's the numbers that we have with our practice.</p> <p>11 Q. Okay. And you personally, can you</p> <p>12 ballpark it, of those 100 plus, what percentage of</p> <p>13 those would be the Exact versus a Boston Scientific</p> <p>14 Advantage?</p> <p>15 A. No, I can't.</p> <p>16 Q. Is it about equal?</p> <p>17 A. It's varied a little bit depending upon</p> <p>18 the year. I think now it's probably pretty close</p> <p>19 to equal.</p> <p>20 Q. Okay. You testified in the past that</p> <p>21 you keep records of complications your midurethral</p> <p>22 sling patients have; is that fair?</p> <p>23 A. Yes, I keep a list of patients who have</p> <p>24 had complications with a TVT that I've had to</p>	<p>1 A. I don't know that it would.</p> <p>2 Q. Would the list tell us what the</p> <p>3 complication was?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And are some of those patients'</p> <p>6 complications pain?</p> <p>7 A. No.</p> <p>8 Q. Are they all erosions or some type of</p> <p>9 urinary dysfunction?</p> <p>10 A. One erosion and the remainder were</p> <p>11 voiding issues.</p> <p>12 Q. Okay.</p> <p>13 MR. CARTMELL: Kelly, I'll also submit a</p> <p>14 request for that list. And I understand there are</p> <p>15 HIPAA issues, but I think if we just get it in a</p> <p>16 format that would not violate that.</p> <p>17 MS. CRAWFORD: You send the request, and</p> <p>18 we will respond to it as to whether we can or can't</p> <p>19 produce it.</p> <p>20 MR. CARTMELL: Okay.</p> <p>21 BY MR. CARTMELL:</p> <p>22 Q. Now, I think you testified in your</p> <p>23 December 2015 deposition that four or five of your</p> <p>24 patients who have had midurethral slings have sued</p>
<p style="text-align: center;">Page 47</p> <p>1 perhaps reoperate on.</p> <p>2 Q. And do you have that list currently?</p> <p>3 A. Not with me right now.</p> <p>4 Q. No, I understand, but in your possession</p> <p>5 somewhere.</p> <p>6 A. Yes, I do.</p> <p>7 Q. And how long have you been keeping that</p> <p>8 list? In other words, what year did you start</p> <p>9 doing that?</p> <p>10 A. Probably from fairly, I mean, for over</p> <p>11 the last ten years or so. I mean, it's -- I don't</p> <p>12 remember if I started it the very first year I was</p> <p>13 doing midurethral slings, but most of the time</p> <p>14 period.</p> <p>15 Q. And does that list just include patients</p> <p>16 that you have had to reoperate on?</p> <p>17 A. The list does, yes.</p> <p>18 Q. How many patients are on that list?</p> <p>19 A. I have taken back to the operating room</p> <p>20 approximately 13 or 14 patients of the slings that</p> <p>21 I've done.</p> <p>22 Q. How many of those were Ethicon products?</p> <p>23 A. I can't tell you that.</p> <p>24 Q. The list would tell us that?</p>	<p style="text-align: center;">Page 49</p> <p>1 you; is that correct?</p> <p>2 MS. CRAWFORD: I'm going to object to</p> <p>3 beyond the scope again. If this is something that</p> <p>4 could have or was asked before the December</p> <p>5 deposition, I think it's beyond the scope of this</p> <p>6 deposition.</p> <p>7 THE WITNESS: Do I answer this?</p> <p>8 MS. CRAWFORD: I think it's -- I mean, I</p> <p>9 can't tell her not to, but I think it's beyond the</p> <p>10 scope of this deposition.</p> <p>11 THE WITNESS: No patients have sued me.</p> <p>12 BY MR. CARTMELL:</p> <p>13 Q. Okay. I misunderstood that testimony.</p> <p>14 You did say that you had a list of 15 patients who</p> <p>15 have sued, I guess, in litigation, but maybe that</p> <p>16 means they have sued Ethicon or other physicians;</p> <p>17 is that fair?</p> <p>18 A. I was provided two lists of patients who</p> <p>19 are -- I don't know how they get on the list for</p> <p>20 either New Jersey or maybe West Virginia --</p> <p>21 possible involvement in litigation against Ethicon.</p> <p>22 So I've seen that list of -- from the two different</p> <p>23 states and two different sources, and on that list</p> <p>24 were 15 patients including patients who have not</p>

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<p>1 even had midurethral slings done or not even had 2 Prolifts done. 3 Q. Okay. So you were somehow involved in 4 the care and treatment with those patients; is that 5 fair? 6 A. Yes. 7 Q. And has a new list since that time been 8 provided with an increased number of patients? 9 MS. CRAWFORD: You know, Tom, I'm just 10 going to object. I believe what we might be 11 talking about is something that is specific to a 12 New Jersey court order, and I'm not going to stop 13 you from asking the questions, but I'm not sure the 14 doctor is in a position to respond adequately to 15 what you're asking her. 16 BY MR. CARTMELL: 17 Q. I'm just asking if there's been an 18 update to that list of 15 that you've seen, doctor. 19 A. I have not been provided with another 20 list since the December. 21 Q. Do you know whether there are any 22 additional patients than that 15 since that time? 23 A. I don't know. 24 Q. Okay. I'm looking through my notes</p>	<p>1 MS. CRAWFORD: Has she personally done 2 any studies? Is that the question? 3 BY MR. CARTMELL: 4 Q. Any research, yes. 5 A. I've had clinical experience with 6 looking at it and working with it, but I haven't 7 done a scientific protocol research. 8 Q. Is the laser-cut mesh stiffer than the 9 mechanical-cut mesh? 10 A. From a -- from a tactile standpoint, you 11 don't really feel a lot of difference with it. I 12 would sort of -- if you were to give them to me, I 13 wouldn't cause -- I wouldn't determine that 14 stiffness was the difference between the two. 15 Q. Have you ever seen any internal Ethicon 16 studies or documents related to the laser-cut mesh 17 being stiffer than the mechanical-cut mesh? 18 A. I don't recall. 19 Q. Okay. Do you have an opinion regarding 20 whether or not the mesh in the TVT degrades in any 21 amount within a woman's pelvis? 22 A. In my experience and my review of the 23 literature I do not think that degradation is a 24 significant or clinical relevant issue within a</p>
<p>1 here. 2 MR. CARTMELL: Can we take a break for 3 about five minutes and I'll try to sort this out 4 and try to pare it down? 5 MS. CRAWFORD: And we'll both take 6 restroom breaks. 7 MR. CARTMELL: All right. Thank you. 8 (Proceedings recessed at 11:43 a.m.) 9 (In session at 11:49 a.m.) 10 BY MR. CARTMELL: 11 Q. Okay. Doctor, we're back on the record 12 after a short break. Are you ready to proceed? 13 A. I am. 14 Q. My understanding is we have five minutes 15 left. Let me ask you, do you know sitting here 16 today what the pore size of the TVT Retropubic mesh 17 is? 18 A. Yes. 19 Q. What is it? 20 A. 1,079 microns, I believe. 21 Q. Okay. And have you done any research or 22 study to determine how stiff or whether there's a 23 difference in stiffness between the laser-cut mesh 24 and the mechanical-cut mesh?</p>	<p>1 patient. 2 Q. Let me just clarify. It sounds like 3 you're not saying there is not some degree of 4 degradation; you're just saying it's not clinically 5 significant. Is that fair? 6 A. No, I'm saying it's not -- definitely 7 not clinically significant, and trying to determine 8 if something is a nonclinically significant 9 degradation is difficult to do. I think that 10 the -- 11 Q. Okay. 12 A. -- studies -- I'm not done. I think 13 that the studies that have looked at degradation, 14 many of them have not shown degradation to occur in 15 explanted specimens, and the difficulty is, as soon 16 as you explant a specimen, you are creating an 17 artifact in any evaluation of that specimen that 18 can be related to just the process of surgically 19 implanting and/or removing. 20 Q. Okay. Let me back up. I'm not sure I 21 was asking for all that. I just want to know, is 22 your opinion that there is some degree, any degree, 23 whether clinically significant or not, of 24 degradation of the polypropylene mesh inside a</p>

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<p>1 woman's vagina -- or do you know?</p> <p>2 A. If you're -- I mean, I can't say that</p> <p>3 there has never been any possible minute amount of</p> <p>4 degradation. I think that that is an impossible</p> <p>5 statement to say one way or the other.</p> <p>6 Q. Okay. So let me ask you this. How many</p> <p>7 mesh implants, whether it be for pelvic organ</p> <p>8 prolapse or for stress urinary incontinence, have</p> <p>9 you removed, either a portion of the mesh or the</p> <p>10 entire mesh?</p> <p>11 A. A lot. Probably --</p> <p>12 Q. How many?</p> <p>13 A. -- somewhere between a hundred and two</p> <p>14 hundred perhaps.</p> <p>15 Q. Okay. Can you ballpark how many of</p> <p>16 those have been stress urinary incontinence</p> <p>17 midurethral slings?</p> <p>18 A. Less than half.</p> <p>19 Q. Okay. And do you refer patients to</p> <p>20 other doctors for them to remove mesh in</p> <p>21 complicated cases?</p> <p>22 A. No.</p> <p>23 Q. You do them yourself?</p> <p>24 A. Yes.</p>	<p>1 you actually had been asked at your prior</p> <p>2 deposition about your use of TVT Retropubic over</p> <p>3 the last years and your use of TVT Exact.</p> <p>4 Do you have an opinion as to whether -- to</p> <p>5 what the difference is in your clinical practice</p> <p>6 between TVT Retropubic and TVT Exact?</p> <p>7 A. Yes.</p> <p>8 MR. CARTMELL: I'm just going -- let me</p> <p>9 just object to the extent I think that exact</p> <p>10 question has been asked in a prior depo, so I do</p> <p>11 think the same thing should apply to you that</p> <p>12 applies to me, but go ahead.</p> <p>13 THE WITNESS: Yes. I think that the</p> <p>14 primary differences between the two are the handle</p> <p>15 that you're using for implanting the device, the</p> <p>16 needle -- the needle size and material, the color</p> <p>17 of the mesh that's being implanted, the sleeve is</p> <p>18 fairly similar, and the handling of the mesh is</p> <p>19 fairly similar.</p> <p>20 MS. CRAWFORD: That's it.</p> <p>21 MR. CARTMELL: Thank you very much,</p> <p>22 everybody.</p> <p>23 MS. CRAWFORD: All right. Tom, first of</p> <p>24 all, I guess this is under the federal rules. She</p>
<p style="text-align: center;">Page 55</p> <p>1 Q. And that hundred to two hundred that you</p> <p>2 have removed polypropylene meshes, has that been --</p> <p>3 well, when has that occurred, over what time</p> <p>4 period?</p> <p>5 A. I mean over, I guess, probably the last</p> <p>6 ten years and stuff, since they have been being</p> <p>7 implanted.</p> <p>8 Q. And you have two partners who also use</p> <p>9 midurethral slings; is that right?</p> <p>10 A. Yes, I do.</p> <p>11 Q. How many have they removed? Do you</p> <p>12 know?</p> <p>13 MS. CRAWFORD: I'm going to object, and I</p> <p>14 also think your time is up, Tom.</p> <p>15 THE WITNESS: No, I don't know. We have</p> <p>16 separate practices.</p> <p>17 MR. CARTMELL: Okay. I think that's all</p> <p>18 the questions I have. Thank you very much.</p> <p>19 MS. CRAWFORD: I just have one follow-up,</p> <p>20 Tom.</p> <p>21 MR. CARTMELL: Okay.</p> <p>22 EXAMINATION</p> <p>23 BY MS. CRAWFORD:</p> <p>24 Q. Doctor, you were asked questions that</p>	<p style="text-align: center;">Page 57</p> <p>1 will read.</p> <p>2 MR. CARTMELL: Okay.</p> <p>3 MS. CRAWFORD: And, number two, the</p> <p>4 exhibits. What do you want to do? There's this</p> <p>5 big binder.</p> <p>6 Doctor, do you care if we send -- do you</p> <p>7 need this stuff back? Shall we make a photocopy?</p> <p>8 THE WITNESS: Yeah, these I'd like</p> <p>9 because these are my originals.</p> <p>10 MS. CRAWFORD: All right. We're going to</p> <p>11 make a photocopy of her originals, which are</p> <p>12 documents -- you don't care about this --</p> <p>13 THE WITNESS: I don't care about that.</p> <p>14 MS. CRAWFORD: -- documents 3 through 8.</p> <p>15 THE WITNESS: 9 -- well, I don't care</p> <p>16 about that one.</p> <p>17 MS. CRAWFORD: And then we'll send those</p> <p>18 with the court reporter and the notebook -- we'll</p> <p>19 send the notebook with the court reporter and the</p> <p>20 original handwritten note with the court reporter.</p> <p>21 Is that okay with you?</p> <p>22 MR. CARTMELL: Yeah, that's fine. I</p> <p>23 would just ask the doctor to maintain the original,</p> <p>24 if she could, and we may ask her to bring those to</p>

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1 trial. 2 MS. CRAWFORD: That's fine. You're going 3 to hold on to these and not lose them. 4 She'll take the copies, then. We'll send 5 the originals with the transcript. 6 MR. CARTMELL: Okay. That sounds great. 7 MS. CRAWFORD: All right. Thanks, Tom. 8 MR. CARTMELL: Okay. See you-all. Have 9 a good day. 10 //	1 ERRATA 2 NAME OF CASE: In re Ethicon 3 DATE OF DEPOSITION: March 25, 2016 4 INSERT REASON FOR CHANGE: 5 1. To clarify the record. 6 2. To conform to the facts. 7 3. To correct a transcription error. 8 Page ____ Line ____ Reason ____ 9 From _____ to _____ 10 Page ____ Line ____ Reason ____ 11 From _____ to _____ 12 Page ____ Line ____ Reason ____ 13 From _____ to _____ 14 Page ____ Line ____ Reason ____ 15 From _____ to _____ 16 Page ____ Line ____ Reason ____ 17 From _____ to _____ 18 _____ 19 NICOLETTE HORBACH, M.D. 20 21 Subscribed and sworn to before me this ____ day of 22 _____ 20 ___. 23 _____ (Notary Public) 24 My Commission expires: _____
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Page 59
1 2 3 I, NICOLETTE HORBACH, M.D., do hereby 4 acknowledge that I have read and examined the 5 foregoing testimony and that the same is a true, 6 correct and complete transcription of the testimony 7 given by me, with the exception of the noted 8 corrections, if any, appearing on the attached errata 9 page. 10 11 _____ 12 DATE NICOLETTE HORBACH, M.D. 13 14 15 16 Subscribed and sworn to before me this ____ day of 17 _____, 20 _____. 18 _____ (Notary Public) 19 My Commission expires: _____ 20 21 22 23 24	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24
	Page 61
	1 C E R T I F I C A T E 2 3 I, LINDA S. KINKADE, Registered Diplomat 4 Reporter, Certified Realtime Reporter, Registered 5 Merit Reporter, Certified Shorthand Reporter, and 6 Notary Public, do hereby certify that prior to the 7 commencement of examination the deponent herein was 8 duly sworn by me to testify truthfully under 9 penalty of perjury. 10 I FURTHER CERTIFY that the foregoing is a 11 true and accurate transcript of the proceedings as 12 reported by me stenographically to the best of my 13 ability. 14 I FURTHER CERTIFY that I am neither counsel 15 for nor related to nor employed by any of the 16 parties to this case and have no interest, 17 financial or otherwise, in its outcome. 18 IN WITNESS WHEREOF, I have hereunto set my 19 hand and affixed my notarial seal this 27th day of 20 March 2016. 21 My commission expires: July 31, 2017 22 _____ 23 NOTARY PUBLIC IN AND FOR 24 THE DISTRICT OF COLUMBIA